

CMDh-IP meeting

15 November 2010

**National switch of product when part of a
European procedure – impact on labelling
(agenda item 6)**

Problem statement

- National switches of authorisations that are part of an MRP/DCP are complex
- Whereas the switch decision is subject to national authority approval, any potential impact on labelling has to be resolved at MRP/DCP level
- There currently is no common understanding how to deal best with mixed legal status in European procedures if the legal status has an impact on labelling as the outcome of a MRP/DCP must be a harmonized product information
- If countries are kept separated in OTC and Rx group of countries in European procedures, the problem is only postponed → how to implement a switch and respective OTC labelling in a country being part of a Rx European procedure?

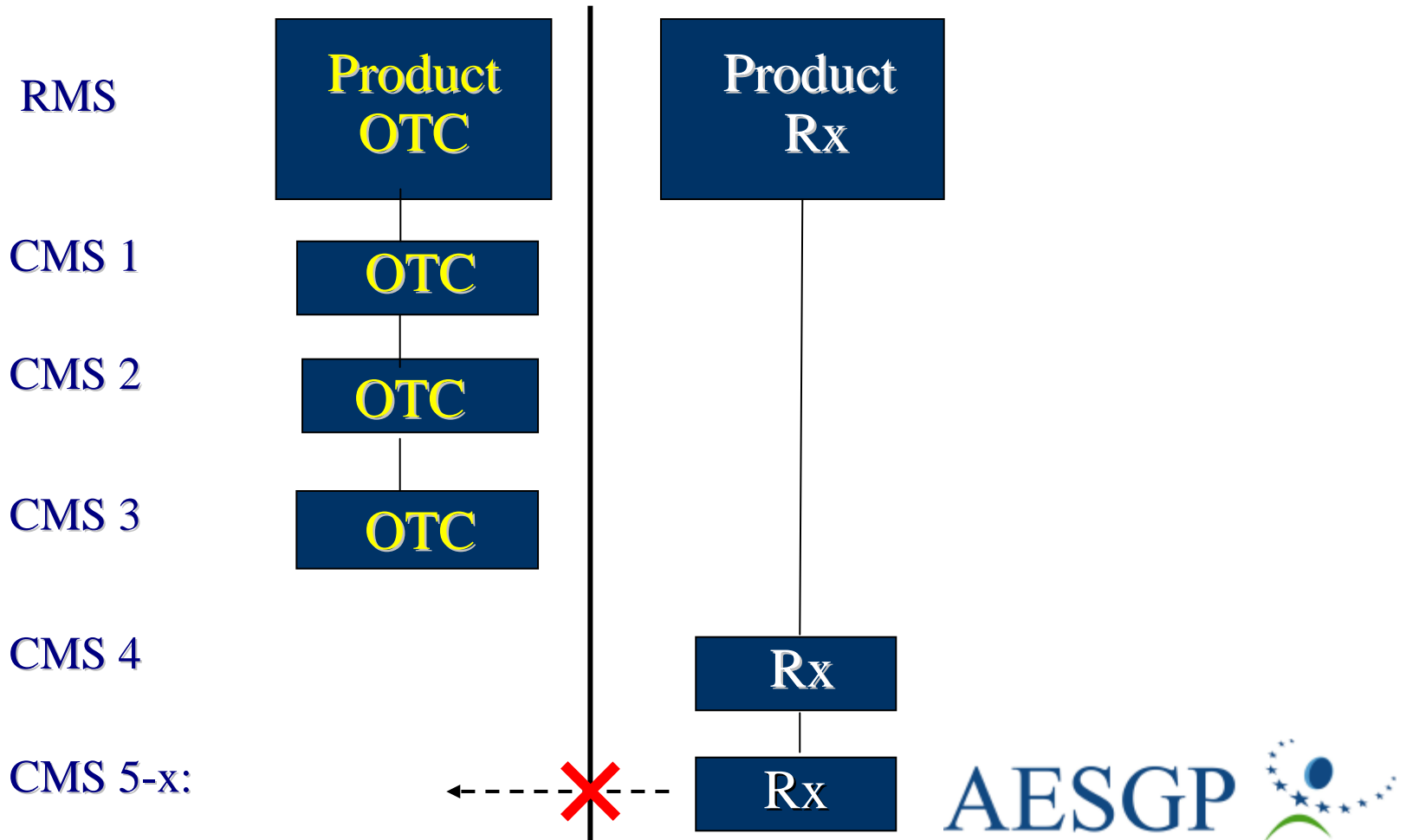
Proposal for discussion

- Agree on Rx and OTC subsets of product information as result of MR/DC procedures, with national implementation of the respective applicable text
- Facilitated by preceding Art. 30 harmonization → Losec as precedence case, but no pre-requisite

Back-up slides

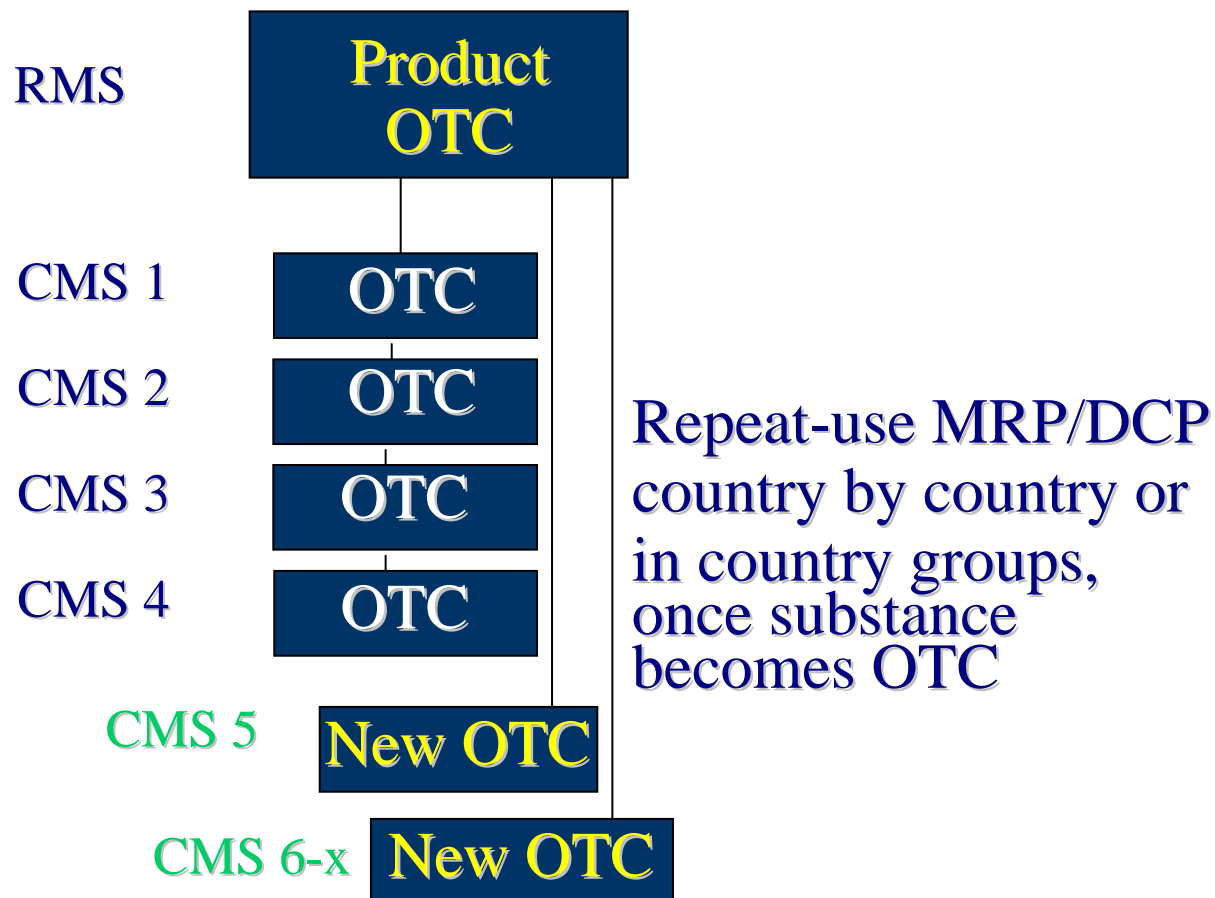
EU regulatory scenario 1: Separate OTC and Rx MRP/DCP

- 1 label per procedure, but prevents a switch in further countries
- cave: dual legal status in RMS or different RMS needed



EU regulatory scenario 2: OTC MRP/DCP only

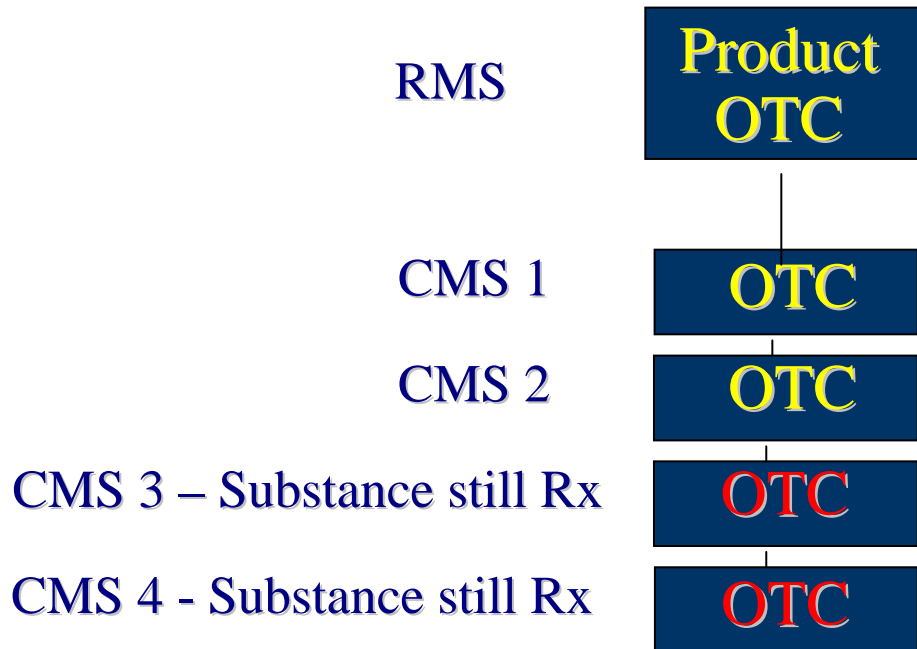
→ Impossible to proactively push switches as in most countries a marketing authorization is needed to apply for a switch; lengthy



EU regulatory scenario 3:

Apply for OTC in all CMS at start of MRP/DCP

→ Switch application itself cannot be filed as part of an MRP/DCP, but is subject to different national procedures and national decision



EU regulatory scenario 4 – proposed case:

Combined Rx/OTC MRP/DCP, subset of product information

→Paves the way for further switches

→Facilitated by Art. 30 harmonization of product information (rf Losec)

